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10/528,224

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6249

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EXAMINER

ELLIS, SUEZU Y

ART UNIT

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1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,224	Applicant(s) NAGAI ET AL.	
	Examiner Suezu Ellis	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL REJECTION

Response to Arguments

Applicant's arguments with respect to claims 1-6, 9 and 10 have been considered but are moot in view of the new ground(s) of rejection.

Specification

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The amendment to add inadvertently omitted material pursuant to 37 CFR 1.57(a) filed March 19, 2008 is not in compliance with 37 CFR 1.57(a) because for the incorporation by reference to be effective as a proper safeguard, the incorporation by reference statement must be filed at the time of filing of the later-filed application. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see

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35 U.S.C. 132(a)). Reference MPEP § 608.01(p). Examiner further requests a certified English translation of the priority application to be submitted.

The amendment filed on March 19, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: a drink or food having strictinin.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claims 1-6, 9 and 10, the original specification did not provide support for a drink or food having strictinin and EGCG3"Me, GCG3"Me, EGCG4"Me, or GCG4"Me. Therefore the addition of strictinin is considered new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1, 5 and 10, claim language recites "**one or more selected from the group consisting of** EGCG3"Me, GCG3"Me, GCG4"Me and strictinin" but further recites in the claim "**wherein EGCG3"Me, GCG3"Me, GCG4"Me and strictinin** are extracted from..." It is unclear if applicant is still claiming one of the group or all the listed ingredients. Please clarify. For examination purposes, claim language will be interpreted as being at least one of those ingredients.

Claims not specifically addressed are indefinite due to their dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 9, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Benifuki or Seishin dai-pan tea, as evidenced by "Shokuhin Kenkyu Seika Jyouhou" (article from the National Food Research Institute).

With respect to claims 1, 5 and 10, EGCG3"Me is inherently found in tea leaves of Benifuki or Seishin-Taipan, (equivalent to "Seishin dai-pan"), as evidenced by "Shokuhin Kenkyu Seika Jyouhou" (paragraphs 1 and 2). Examiner further notes that the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See MPEP § 2112. Regarding claim 9, the claimed masking agent could be anticipated by the sugar or milk, ordinary and well known green tea additives.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (EP 1 157 693).

With respect to claims 1-6 and 10, Yamamoto et al. discloses a beverage comprising epigallocatechin-3-O-(3-O-methyl)gallate (EGCG3"Me) [0014] as an anti-allergic agent, wherein the epigallocatechin-3-O-(3-O-methyl)gallate is obtained as tea extract from "Seishin-Taipan", (equivalent to "Seishin dai-pan"), "Benihomare", "Benifuji", and/or "Benfuki" tea leaves [0024]. Yamamoto et al. fails to expressly disclose the EGCG3"Me being contained in the claimed amount. Yamamoto et al. fails

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to expressly disclose the EGCG3"Me being contained at 0.01-1000 mg/L to daily intake of 0.3-3,000 mg. However, Yamamoto et al. does disclose the EGCG3"Me may be used in appropriate amounts, such as 5-300 mg/kg per day, depending on the application (food/drink, cosmetic, etc) [0034], [0035]. It would have been obvious to one of ordinary skill in the art to modify the intake amount of EGCG3"Me depending on the desired application. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 9, Yamamoto et al. discloses the drink comprises sweetening agents, thereby masking any bitterness the tea may have [0031].

With respect to claim 10, Yamamoto discloses epigallocatechin-3-O-(3-O-methyl)gallate (anti-allergic agent) is derived from tea leaves and can be used as such or as powders, or used in combination with drink materials or carriers acceptable for preparation of drink [0030]. Yamamoto et al. also discloses the epigallocatechin-3-O-(3-O-methyl)gallate is extracted from "Seishin-Taipan", (equivalent to "Seishin dai-pan"), "Benihomare", "Benifuji", and/or "Benfuki" tea leaves [0024]. Yamamoto et al. fails to expressly disclose a tea bag containing the tea leaves. However, it is well known in the art for tea to be packaged in tea bags. It would have been obvious design choice to one of ordinary skill in the art to package the tea of Yamamoto in tea bags depending on the user's preference and for ease of use (less clean up than loose tea leaves). Yamamoto et al. also fails to expressly disclose the EGCG3"Me being contained at 0.01-1000 mg/L to daily intake of 0.3-3,000 mg. However, Yamamoto et al. does disclose the

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EGCG3"Me may be used in appropriate amounts, such as 5-300 mg/kg per day, depending on the application (food/drink, cosmetic, etc) [0034], [0035]. It would have been obvious to one of ordinary skill in the art to modify the intake amount of EGCG3"Me depending on the desired application. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 1-6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Shokuhin Kenkyu Seika Jyohou" (article from the National Food Research Institute) in view of Yamamoto et al.

With respect to claims 1-6, "Shokuhin Kenkyu Seika Jyohou" discloses epigallocatechin-3-O-(3-O-methyl)gallate is found in tea leaves and used as an anti-allergenic, where the EGCG3"Me is extracted from Benifuki tea leaves or from "Seishin-Taipan", (equivalent to "Seishin dai-pan"), (paragraphs 1 and 2). Although the article fails to expressly disclose the tea leaves is used for food or drink, it is well known in the art to use tea leaves for drinking purposes. While the article fails to disclose the exact amount of EGCG3"Me in the tea, it would have been obvious to one of ordinary skill in the art to modify the intake amount of EGCG3"Me depending on the desired application, as taught by Yamamoto et al. [0034], [0035], or depending on how strong the user prefers their tea. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 9, the article fails to expressly disclose the food or drink comprising a masking agent to mask the bitterness. However, it is well known in the art to add sugar to tea to make it sweeter and thereby masking bitterness. It would have been obvious to one of ordinary skill in the art to include a masking agent in order to provide the predictable result of not have a bitter tea.

With respect to claim 10, "Shokuhin Kenkyu Seika Jyohou" discloses epigallocatechin-3-O-(3-O-methyl)gallate is found in tea leaves and used as an anti-allergenic, where the EGCG3"Me is extracted from Benifuki tea leaves (paragraphs 1 and 2). Examiner further notes that the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See MPEP 2112. Although the article fails to expressly disclose the tea leaves is used for food or drink, it is well known in the art to use tea leaves for drinking purposes, thereby providing a drink with an anti-allergenic function. While the article fails to disclose the exact amount of EGCG3"Me in the tea, it would have been obvious to one of ordinary skill in the art to modify the intake amount of EGCG3"Me depending on the desired application, as taught by Yamamoto et al. [0034], [0035], or depending on how strong the user prefers their tea. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. The article also fails to expressly disclose a tea bag containing the tea leaves. However, it is well known in the art for tea to be packaged in tea bags. It would have been obvious design choice to one

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of ordinary skill in the art to package the tea of Yamamoto in tea bags depending on the user's preference and for ease of use (less clean up than loose tea leaves).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10 and 11 of U.S. Patent No. 6,638,524.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,638,524 are drawn to a food/beverage (tea) that comprises strictinin wherein the strictinin is contained in an amount of 5-100 mg/kg per day. While the claims of U.S. Patent No. 6,638,524 fails to

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expressly recite the same amount of strictinin as in the instant application, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

*/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615*